

The usefulness of 24 hour Holter monitoring in asymptomatic pacemaker patients in early post-implantation period

Jerzy Krzysztof Wranicz, Michał Chudzik, Iwona Cygankiewicz,
Artur Klimczak and Jan Henryk Goch

Department of Cardiology Medical University of Łódź, Poland

Abstarct

Background: *Twenty four hour Holter monitoring (HM) in an early post-implantation period in asymptomatic patients is considered as class IIb according to the ACC/AHA guidelines. It seems that post-implantation assessment extended by 24 hour HM in these patients might shorten hospitalization and increase safety of these patients. This aspect has not been widely discussed so far. The aim of our study was to evaluate pacing and sensing disturbances in asymptomatic patients with proper parameters of single and double chamber pacemakers.*

Methods: *Studied group included 236 patients implanted with Biotronik Actros S (single chamber) (group I — 130 patients) and Biotronik Actros D or Axios D (group II — 106 patients) pacemakers. In all the patients 24 hour HM was performed 1–6 days after implantation (mean 3.4) in order to assess all pacing and sensing disturbances.*

Results: *Sensing disturbances were found in 2 patients from group I and 22 patients from group II (the most frequent pacemaker failure was atrial undersensing followed by ventricular oversensing-T wave stering). In 1 patient from group I atrial failure to pace was observed. In whole group pacing/sensing disturbances were found in 23% of patients, nevertheless they did not provoke any hemodynamic consequences.*

Conclusions: *In an early post-implantation period pacemaker disturbances occur in 23% of asymptomatic patients being more frequent in patients with dual chamber pacemaker. Atrial undersensing and ventricular oversensing are the most common disturbances, nevertheless having no hemodynamic consequences they are not life-threatening. Detection of these episodes in an early post-implantation period allows for early change in pacemakers' parameters and thus decreasing risk of rehospitalization. We confirmed the low usefulness of HM in patients with single chamber pacemaker early after implantation. (Folia Cardiol. 2006; 13: 390–395)*

Key words: Holter monitoring, pacemakers, pacemaker malfunction

Introduction

According to AHA/ACC standards in asymptomatic pacemaker patients in an early post-implantation period, performing the 24-hour ECG Holter monitoring (HM) is considered as class IIb indication for this testing [1]. It is an alternative or a supplement to constant telemetric monitoring. A class IIb means

Address for correspondence: Jerzy K. Wranicz, MD PhD
Department of Cardiology Medical University of Łódź
Sterlinga 1/3, 91–425 Łódź, Poland
Tel./fax: +48 42 636 44 71
e-mail: holter@csk.umed.lodz.pl
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Table 1. Clinical characteristics of studied patients.

Feature	Group I (n = 130)	Group II (n = 100)
Men	56 (43%)	58 (58%)
Age (years)	52–86 (mean: 72 ± 7)	52–78 (mean: 67.5 ± 7.3)
Left ventricle ejection fraction	39–81% (mean: 61% ± 18%)	42–74% (mean: 56 ± 12%)
Indications for implantation		
Sick sinus syndrome	0	52 (52%)
Atrio-ventricular misconduction	0	43 (43%)
Persistent atrial fibrillation	130 (100%)	0
Other	0	5 (5%)

that research results or experts' opinions are not fully supportive with little usefulness of this procedure.

Modern pacemakers and endocardial electrodes are devices of great reliability, comparing to those from the very beginnings of electrotherapy [2–7]. On the other hand, major technological progress, new algorithms of pacemaker function, new advanced functions and growing expectations to their operating not only as pacing devices cause that the ACC/AHA guidelines from 6 years ago may be partially no longer up-to-date and the diagnostic spectrum of HM may be widened [8]. Apart from therapeutic aspects, costs play a progressively larger role in patient's management [9, 10]. One of their major components is the length of the hospitalization period, the shortening of which, remaining safe for the patient after the pacemaker implantation, may be an important factor in lowering them. Owing to that, new methods of evaluating patient's condition in the early post-implantation period are being considered, proving pacemaker's correct pacing and sensing [11]. Until now, methods used to assess stimulating devices, such as standard 12-lead ECG, control of the parameters of stimulation, radiography not always have revealed possible malfunctioning of pacing devices [12]. It seems that widening the routine evaluation of the patient's condition in the early post-implantation period in asymptomatic patients with HM may shorten the hospitalization period and improve patient's safety.

The aim of this study was to evaluate of pacing and sensing of pacemakers in 24-hour HM in the early post-implantation period, in asymptomatic patients with correct parameters of the implanted single and double chamber pacemakers.

Methods

Initially, 236 patients, who had pacemakers implanted in the years 1998–2002 in the Department

of Cardiology and Cardiosurgery of the Medical University of Lodz, were included in the study. The patients were divided into two groups: group I — 130 patients with implanted Actros S (Biotronik) single chamber pacemaker, group II — 106 patients with implanted Actros D (R) or Axios D (R) double chamber pacemaker. The clinical characteristics is shown in Table 1.

Implantation procedure

The implantations were performed by experienced physicians (over 500 performed operations) in accordance with the Polish Cardiological Society standards [13]. Every patient had a passive fixation electrode implanted: Synox SX 53–JPB into right atrium, and Synox 60–BP into the appendage of the right ventricle. Double puncture (one for every electrode) of left subclavian vein was the method of choice in implantation.

The correct positioning of the electrodes was assessed using radiologic examination (radiography). Intra cardiac ECG (IEGM), with the so-called "intrinsic deflection" performed in every patient, was an additional criterion of correct electrode fixation.

The following electrical parameters, measured with Biotronik ERA 300 analyzer, were considered correct during the implantation procedure:

- threshold of stimulation both in atrium and in ventricle, with impulse width of 0.5 ms: < 0.5 V;
- amplitude of P wave measured in bipolar configuration: > 3 mV in five subsequent complexes;
- amplitude of R wave measured in bipolar configuration: > 10 mV in five subsequent complexes.

Resistance measuring was performed using Biotronik PMS 1000 programming device.

After connecting electrodes to the stimulator, with original factory settings and in magnetic rhythm, ECG record from limb leads I, II, III was performed and the correctness of pacing and sensing was analysed.

Table 2. Programmed parameters of single and double chamber pacemakers in an early post-implantation period.

Parameter	Programming method group I	Programming method group II
Modes of pacing	Ventricle pacing mode	Double chamber pacing mode
Basic pacing frequency	80/min	60/min or 70/min
Hysteresis	Off	Off
Amplitude of the impulse in atrial and ventricular channel with impulse width of 0.4 ms	3.6 V	3.6 V
Atrium sensing	Does not occur	0,5 mV
Ventricle sensing	2.5 mV	2.5 mV
Atrial refraction period	Does not occur	450 ms
Ventricular refraction period	250 ms	250 ms
Upper rate	Does not occur	120/min

Post-operative evaluation of stimulation parameters

In the period from 24 hours to 5 days (av. $3.2 \pm \pm 1.3$ days) after implantation, using PMS 1000 programming device, the parameters of stimulation were evaluated, considering correct:

- threshold of stimulation in atrium with impulse width 0.4 ms: < 1.5 V;
- threshold of stimulation in ventricle with impulse width 0.4 ms: < 1 V;
- average amplitude value of P wave measured for 12 s in subsequent complexes: > 2 mV;
- average amplitude value of R wave measured for 12 s in subsequent complexes: > 8 mV;
- electrode resistance from 300 to 1500 Ohm.

The parameters of pacing were measured in unipolar configuration, and parameters of sensing in bipolar. Only patients with correct parameters were included in the study. The settings of the stimulator after implantation is shown in Table 2.

To assess correct sensing intracardial electrocardiogram from atrial and ventricular channel was performed.

24-hour Holter ECG monitoring

In every patient in the period between 1 and 6 days (av. 3.4 ± 1.2 days) after implantation 24-hour HM was performed, with accordance to ACC/AHA standards.

Registration was performed using 3-channel Oxford MR 45-3 registering devices with pacing option (on analog recording tapes TDK AD 60) using typical leads CS-2, CM-5 and IS. The analysis of registration was performed using Oxford Medilog Excel 3 system, applying automatic analysis using stimulator programme and manual record

verification. The commonly accepted analysis standards according to ACC/AHA guidelines were used.

In HM record pacing and sensing evaluation was performed. The disturbances found were classified according to the following parameters: all pacing and sensing disturbances, failure to pace, failure to sense. The latter were divided into: oversensing and undersensing.

Failure to pace was stated when the effective stimulation did not occur behind stimulator peak; undersensing — stimulator peaks behind the peak of P wave and/or behind R wave in QRS complex; oversensing — too long peak-to-peak period (longer than basic pacemaker rhythm).

Results

Pacing and sensing parameters in early post-operation period

Into the final analysis, 230 patients were included: 130 patients from group I and 100 patients from group II, with correct pacing and sensing parameters. From 6 patients not included in the study, 4 had stimulation threshold over 1.5 V, in the remaining 2 the average P wave potential was under 2.0 mV. In the remaining patients, both in group I and II, correct pacing and sensing values were found. Those parameters in both post-implantation groups are shown in Table 3.

Evaluation of pacing and sensing disturbances in 24 hour ECG Holter monitoring

Tables 4 and 5 show the evaluation of pacing and sensing disturbances in patients with implanted single and double chamber pacemakers in early post-implantation period. In group I sensing

Table 3. Pacing and sensing parameters in an early post-implantation period in patients with one and double chamber pacemakers.

	Group I	Group II
Atrium pacing threshold [V]	Does not occur	0.64 ± 0.43
Ventricle pacing threshold [V]	0.61 ± 0.6	0.62 ± 0.5
P wave amplitude [mV]	Does not occur	3.1 ± 1.1
R wave amplitude [mV]	12 ± 5.2	14.4 ± 6
Atrial electrode impedance [Ohm]	Does not occur	752 ± 335
Ventricular electrode impedance [Ohm]	684 ± 256	705 ± 428

Table 4. Pacing and sensing disturbances in patients with single chamber pacemaker found during 24 h Holter monitoring in an early post-implantation period — group I (n = 130).

Failure to sense: oversensing — ventricle	1 (0.8%)
Failure to sense: undersensing — ventricle	1 (0.8%)
Failure to pace — ventricle	0
Disturbances overall	2 (1.5%)

Table 5. Pacing and sensing disturbances in patients with double chamber pacemaker found during 24 h Holter monitoring in an early post-implantation period — group II (n = 100).

Failure to sense: oversensing	
atrium	0 (0%)
ventricle	10 (10%)
Failure to sense: undersensing	
atrium	12 (12%)
ventricle	0
Failure to pace	
atrium	1 (1%)
ventricle	0
Disturbances overall	23 (23%)

disturbances characterized as undersensing and oversensing were found overall in two patients. In none of the patients insufficient or missing ventricular stimulation was found.

In 12 patients from group II, despite the fact that standard sensing was set in bipolar configuration, undersensing-type disturbances of P wave were found. The most often found sensing disturbance in this group in ventricular channel was oversensing — sensing with T wave. That caused transitional bradycardia with pacemaker function pauses with maximum of up to 1600 ms, with no clinical symptoms. Those disturbances appeared in different time of the day, regardless of patient's activity.

There were no pacing disturbances found in ventricular channel, only in 1 patient failure to pace in the atrium was found — in only 4 subsequent complexes, followed by effective ventricular pacing.

Despite the fact that the above mentioned disturbances were found overall in 23% of patients, they did not cause pauses with hemodynamic after-effects.

Discussion

Performing Holter monitoring in asymptomatic patients with implanted pacemaker was subject to only few publications [15–17]. It was proved in most of them that in patients with VVI pacemakers and unipolar electrodes disturbances in stimulating devices functioning may be found, amongst which oversensing was the most common. This phenomenon was observed despite the fact that correct pacing and sensing parameters were confirmed [18]. It needs to be stated that this research was performed in the long term after implantation (av. 3.5 years). However, there is a lack of publications assessing the function of single and double chamber pacemakers in the early post-implantation period. This may happen for two different reasons: first, introducing bipolar electrodes was supposed to eliminate oversensing problem completely — the most common cause of sensing disturbances in patients with unipolar electrodes, second, the ACC/AHA guidelines for evaluating asymptomatic patients using Holter monitoring, published in 1999 and valid to this day, were classified as IIb — that means that the opinion of most experts was not supportive for performing HM in such circumstances. Consequently, this issue was beyond the interests of most researchers.

We were convinced to perform this research in patients with implanted single chamber pacemaker by the need of assessing whether introducing

bipolar electrode really eliminates the problem of sensing disturbances, described in such a high percentage in patients with VVI pacemakers and unipolar electrodes.

Today's double chamber pacemakers are devices with many programmable functions and complex diagnostical algorithms. This validates the question whether the parameters of pacing and sensing, programmed in standard manner after the procedure, ensure correct pacemaker function and patient's safety. It is the matter of major importance in search of the methods for shortening hospitalization period and therefore lowering the costs of management. Because of low availability of constant telemetric monitoring methods, HM may be an efficient alternative in the early evaluation of the patient after PM implantation. In our study HM showed differences in the number of pacing and sensing disturbances in both groups. They were sporadic in group I (only 2 patients — 1.6%) but in group II they occurred in 23% of patients.

In both groups, in none of the patients disturbances in chamber stimulation were found. Incorrect pacemaker function did not cause relevant pauses and therefore would not have been an obstacle for safely discharging a patient from hospital in the early post-operation period.

In group I patients, under- and oversensing incidents were sporadic, they occurred in only 2 patients. It has confirmed the opinion that introducing bipolar electrodes significantly decreased the prevalence of sensing disturbances. In our study, quoted before, concerning oversensing was found in 3.6% of asymptomatic patients with VVI pacemakers with unipolar electrodes. Moreover, those disturbances lead to occurrence of pauses in pacemaker function — with maximum up to 2600 ms. In group II undersensing in atrium channel was found in 12% of patients. Also other publications confirmed that undersensing in atrium channel is the most common sensing disturbance [19]. In our patients, the sensitivity in atrium channel of 0.5 mV allowed lowering this value to 0.1 mV. Then, however, the risk of occurring atrial oversensing must be taken into account [20, 21]. Intra cardiac electrograms (IEGM) are required to assess sensing when lowering the value of this parameter. Oversensing in ventricular channel was found in 10% of patients. The longest pause registered was 1600 ms.

It is well known that the oversensing phenomenon in ventricular channel may result in slowing pacing frequency and be the reason of unnecessary hospitalization because of suspecting pacemaker

malfunction. Finding of these disturbances, thanks to HM, in early post-implantation period allows changing pacemaker parameters (by correcting re- fraction period and/or sensing) and therefore avoiding a next hospitalization. In the group of patients taken into account, no atrial oversensing or ventricular undersensing was found.

It needs to be emphasised that all disturbances found in HM were not a danger to the patient's life and/or health. All of the disturbances found were managed by correcting pacemaker parameters. Proper functioning of PM was then confirmed in the next Holter examination.

The topic of this study has never been discussed in the available literature. This evaluation is the first try of analysing of usefulness of 24-hour ECG in assessing the correctness of pacing in asymptomatic patients in the early pacemaker post-implantation period. The urge to discharge the patient from hospital as early as possible after pacemaker implantation is due to lowering the costs of hospitalization, and full safety of those patients must be ensured. This forces using new diagnostic features which give greater feeling of safety both to the patient and to the physician who decides to shorten the hospitalization period after the pacemaker implantation procedure.

The results of our study proved only a slight value of 24-hour HM in asymptomatic patients with single chamber pacemakers and bipolar electrodes, which is in accordance to ACC/AHA guidelines (class IIb).

However, conclusions different than the mentioned above come from evaluating the patients with double chamber pacing. In this group HM in the early post-implantation period revealed sensing disturbances, the correction of which, although they did not endanger patients' life and/or health, allowed better programming of the pacemaker and avoiding possible hospitalization because of sensing disturbances.

Therefore, it seems to be reasonable to consider performing 24 hour HM in asymptomatic patients with double chamber pacemaker, in early post-implantation period.

Paradoxally, introducing further pacemaker functions may lead to increasing the percentage of sensing disturbances, undetectable in routine control but only in HM. Moreover, the optimal individualization of pacemaker parameter is possible mostly on the basis of Holter ECG examination.

Perfecting diagnostic function in pacemakers may allow in the future to register IEGM and therefore to limit the legitimacy of HM in those patients.

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